Congress of the United States
Washington, DC 20515

February 7, 2020

The Honorable Alex Azar
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Stephen Hahn, M.D.
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Secretary Azar and Commissioner Hahn:

We are deeply concerned about the Gynuity Health Projects clinical trial (ClinicalTrials.gov Identifier: NCT03269279) conducted in Burkina Faso beginning May 20, 2017 and was scheduled for completion by the end of 2019.

This study recruited Burkinabe women who were 13-22 weeks pregnant – the second trimester – to test the effectiveness of mifepristone and misoprostol for an abortion. As you know, mifepristone (Mifeprex) is intended to end the life of the unborn child up to 10 weeks' gestation. Current U.S. Food and Drug Administration (FDA) guidelines for Mifeprex state that women who are more than 70 days or ten weeks pregnant should not take the drug. The FDA medication guide lists several adverse effects, including heavy bleeding, and indicates that 2-7% of women taking the drug will need a surgical procedure to complete the abortion or stop the bleeding.[1] A Finnish study, which included "all women in Finland undergoing induced abortions from 2000-2006" found that adverse events for chemical abortions were *fourfold* higher than surgical abortions.[2] Chemical abortion risks are only amplified after the 70-day period. In an Australian study, 33% of chemical abortions in the second trimester resulted in surgical intervention and 4% resulted in a significant hemorrhage.[3]

We find it troubling that Burkina Faso was selected as the location for this clinical trial, where poor health and safety conditions endanger the participants involved. Burkina Faso faces a severe lack of medical professionals—there is fewer than one (.6) physician for every 10,000 people.[4] Africa also faces frequent blood shortages, and the clinical trial's director, Dr. Blandine Thieba, even acknowledged the dire need for blood bags in the country during the study.[5] Further, of the 23,000 women treated for abortion-related complications in 2008, 15,000 suffered serious

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[1] www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf
[2] citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.920.7430&rep=rep1&type=pdf
[3] www.racgp.org.au/download/documents/AFP/2011/May/201105mulligan.pdf
[4] www.who.int/gho/health_workforce/physicians_density/en/
[5] www.realclearinvestigations.com/articles/2019/12/22/us_abortion_trial_in_impoverished_burkina_faso_121725.html

complications but did not receive the care they needed, according to the Guttmacher Institute.[6] Clearly, these are the least appropriate conditions for any high-risk clinical trial.

We urge the FDA to carefully review this trial should it be used in support of an investigational new drug (IND) application. We are deeply concerned that this trial was not conducted in accordance with good clinical practices. We are also concerned that this clinical trial may have violated 21 C.F.R. 56.111, specifically, that the subjects of the study were unnecessarily exposed to risk and that there were not appropriate safeguards in place to protect the rights and welfare of pregnant women, let alone their unborn children.

We are also seeking clarification on whether this trial was approved by an Institutional Review Board (IRB). If it was approved by an IRB, we would like confirmation that the review board took into account ethical and safety considerations for the women involved in the study including items such as inadequate blood supplies, limited access to physicians, and the precedent of women suffering from a lack of quality care following abortion-related health complications.

If there is no IND in effect, we are seeking clarification if the independent ethics committee that approved the study took into account the ethical and safety concerns previously stated. Should Gynuity Health Projects request a waiver for any applicable requirements listed under 21 C.F.R. 312.120, we respectfully request the FDA to deny the request.

Considering the concerns just presented, we would ask for your immediate attention to the following requests:

- What measures have the U.S. Department of Health and Human Services (HHS), the National Institutes of Health (NIH), and the FDA taken to prevent the exploitation of women in private clinical trials, especially of women in developing countries?
- Please provide all releasable details of abortion-related clinical trials held in developing countries where a U.S. researcher is a sponsor, collaborator, or investigator.
- How does the IRB denial rate on trials related to abortion-inducing drugs compare to denial rate on other high-risk studies?
- Please direct HHS to review and revise statutory standards for IRBs.

Understanding the inherent confidentiality of the IND process, we are requesting to review the following information in camera at the Department of Health and Human Services:

- Documents and information related to the name of the IRB that approved this trial;
- Documents and information related to the complete project application provided to the IRB;
- Any other documents and information related to the IRB's approval of this trial.

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[6] www.guttmacher.org/fact-sheet/abortion-burkina-faso

We thank you for your service to our nation and we are encouraged by this Administration's work to protect and defend the dignity of the unborn and promote ethical research. We look forward to your response no later than February 28, 2020.

Sincerely,

Mark Meadows
Member of Congress

Ron Estes
Member of Congress

Christopher H. Smith
Member of Congress

Vicky Hartzler
Member of Congress

Rick Crawford
Member of Congress

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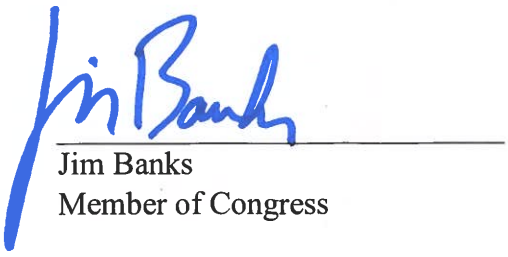

Jim Banks
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Bill Flores
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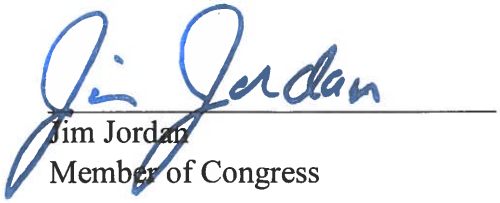

Jim Jordan
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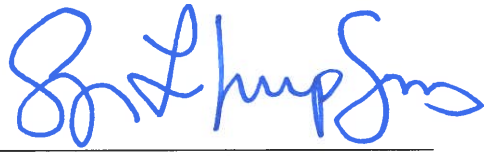
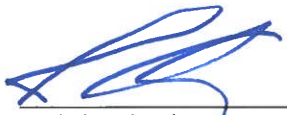


Gregory Murphy, M.D.
Member of Congress



Ralph Abraham, M.D.
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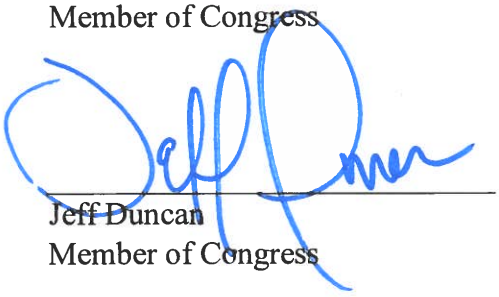

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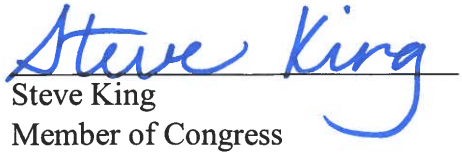
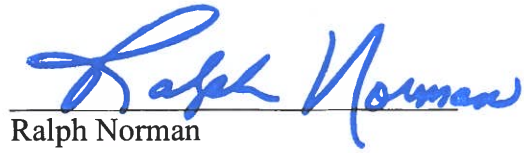
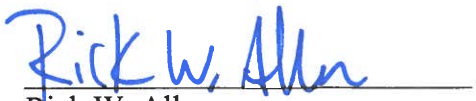


Steve King
Member of Congress



Ralph Norman
Member of Congress



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Roger Marshall, M.D.
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Gus M. Bilirakis
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Pete Olson
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Dan Bishop
Member of Congress

Bruce Westerman
Member of Congress

CC: Director Garret Grigsby, HHS Office of Global Affairs; Dr. Francis Collins, NIH Director